

**REMARKS**

Claims 37-41\* and 43-58 are pending in the present application. Claims 49-58 were previously withdrawn from consideration as drawn to a non-elected invention. Please note that claim 42 was previously cancelled. Accordingly, claims 37-41, 43-48 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

***Claim Rejections – 35 USC § 103*****Claims 37-41\* and 43-44**

Claims 37-41\* and 43-44 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,984,933 to Yoon (“Yoon”), further in view of WO 02/053011 A2 to Friedman (“Friedman”). The Office Action alleges that Yoon teaches the Applicants’ invention substantially as claimed, but concedes that Yoon fails to teach clips comprising two tissue-piercing legs joined by a loop with the tether passing through the loop transversely to the legs. The Office Action relies on Friedman to cure this omission, and alleges that it would have been obvious for one of ordinary skill in the art at the time of the invention to use the clips of Friedman with the delivery device of Yoon. Applicants strongly disagree.

First, Yoon not only fails to teach clips comprising two tissue-piercing legs joined by a loop, but Yoon also fails to teach at least two clips in a closed tissue-piercing position and at least one clip is slidable. To re-iterate, Yoon fails to disclose at least the following claim limitations:

1. The at least two clips are in a closed tissue-piercing position.
2. At least one clip is slidable on the tether.

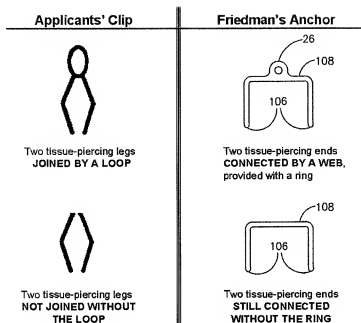
The Office Action relies on FIG. 38 to assert that the “clips” depicted there are in a closed tissue-piercing position in both its first and second deployed configuration and that at least

one clip is slidable. However, the knotting elements shown in FIG. 38 are not capable of a closed, tissue-piercing configuration. According to the description in Yoon, the knotting elements shown in FIG. 38 are balls (*see* col. 19, ll. 50-53) that “do not require plastic deformation or spring closure of opposed surfaces” (col. 19, ll. 29-30). Furthermore, Yoon teaches “...a suture supply includes a length of suture material **1618** having a plurality of knotting elements **1620**, **1620a**, **1620b**, **1620c**, **1620d**, and **1620e** secured thereto at spaced locations” (col. 19, ll. 43-45). Since these knotting elements do not have a tissue-piercing configuration and are at secured at spaced locations, they are not in a closed tissue-piercing position where at least one clip is slidable. The disclosure pointed to by the Office Action fails to disclose each and every element of the claim limitation as indicated above, and no disclosure in Yoon remedies these omissions.

Second, Friedman fails to teach a clip with two tissue-piercing legs joined by a loop. The tissue-piercing ends 106 of Friedman are “connected by a web portion 108...” where “The web portion 108 of each anchor member 10 is provided with a suture-retaining form 26...” (*see* p. 10, ll.22-23, 27-28). According to Friedman, the loop 26 is simply attached along the web portion and does not join the tissue-piercing legs. More specifically, when two members are joined by a third member (whether or not the first, second, and third members are integrally formed or are discrete elements), the third member is a juncture between the first two members. In other words, removal of the third member would decouple the first two members. This is illustrated below.

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\* Claim 42 was cancelled in the Amendment filed March 27, 2009



Since the loop 26 is not a juncture between the two tissue-piercing ends 106, the tissue-piercing ends are not “joined by” the loop 26. As such, Friedman fails to disclose a clip with two tissue-piercing legs joined by a loop.

Third, one of ordinary skill in the art would not use the Friedman clip with the Yoon delivery device because Yoon teaches away from using a clip that is incapable of securing a suture to form a knot. The following descriptions from Yoon exemplify this teaching.

“It is extremely important for knotting or tying of sutures to be consistently performed to provide a stitch with controlled, non-slipping, tension; and, to this end, it is common for surgeons to tie double knots...” (col. 1, ll. 53-56)

“The attachment site of a knotting element according to the present invention is a location at which the knotting element is carried by the suture material either by immovable fixation or by sliding engagement, and the grasping site of a knotting element according to the present invention is a location at which the knotting element non-releasably engages the suture material to

form a stitch such that a knotting element has the effect of tying a knot in a length of suture material.” (col. 7, ll. 62-67 and col. 8, ll. 1-3)

Friedman, however, describes anchors that are not configured to non-releasably secure a suture, as indicated by the descriptions reproduced below.

“It is one of the objects of the present invention to provide an anchor member which allows manipulation of a suturing filament after implantation of the anchors.” (pg. 3, ll. 4-6)

“The surgeon can connect the anchors in any manner... Should the result not be satisfactory, the suturing filament 32 is easily removed and another pattern can be used.” (pg.7, ll. 19-20)

Based on the above Friedman descriptions, as well as FIGS. 12 and 13, it is clear that the Friedman clips are not intended to form, or are capable of forming, a stitch to effect a knot. Since Yoon places an emphasis on the importance of knot-tying, an ordinary artisan would not look to modify the Yoon device with the Friedman clips, which cannot effect a knot. In fact, modifying the Yoon device with the Friedman clips would render the Yoon invention inoperable for its intended use, i.e., unable to knot or tie sutures (*In re Gordon*, 733 F.2d 900, 221 USPQ 1125). “If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” (MPEP 2143.01 (V))

As described above, one of ordinary skill in the art would not find it obvious to combine Yoon and Friedman to obtain the Applicants’ device as claimed. Furthermore, even if one were able to combine Yoon and Friedman (which Applicants do not concede), the combination would still fail to disclose each and every element of claim 37, since neither Yoon nor Friedman disclose a tethered clip assembly wherein the clips comprise two tissue-piercing legs joined by a loop. For at least these reasons, a rejection of independent claim 37 under 35 U.S.C. §103(a) cannot stand. Applicants respectfully request the rejection of the pending claims be withdrawn, and submit that claims 37-41\* and 43-44 are patentable.

Claims 45, 46, and 48

Claims 45, 46, and 48 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoon and Friedman, as applied to claim 37 above, and in view of U.S. Patent No. 5,524,630 to Crowley ("Crowley"). The Office Action alleges that Yoon and Friedman disclose the claimed invention except for a visualization device, and rely on Crowley to remedy this omission. Applicants strongly disagree with this rejection.

Yoon and Friedman were discussed in detail above with respect to claim 37 (from which claims 45, 46, and 48 depend), where it was established that the combination of Yoon and Friedman fail to teach or disclose clips that have a tissue-piercing position and two tissue-piercing legs joined by a loop. Furthermore, modifying Yoon with Friedman would render the Yoon device unsatisfactory for its intended purpose. Crowley fails to cure these deficiencies. As such, Applicants respectfully request that the rejection of claims 45, 46, and 48 under 35 U.S.C. §103(a) be withdrawn.

Claim 47

Claim 47 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoon, Friedman, and Crowley as applied to claim 45 above, further in view of U.S. Patent No. 5,766,240 to Johnson ("Johnson").

Yoon and Friedman were discussed in detail above with respect to claim 37 (from which claim 47 depends), where it was established that the combination of Yoon and Friedman fail to teach or disclose clips that have a tissue-piercing position and two tissue-piercing legs joined by a loop. Furthermore, modifying Yoon with Friedman would render the Yoon device unsatisfactory for its intended purpose. Both Crowley and Johnson fail to cure these deficiencies. As such, Applicants respectfully request that the rejection of claim 47 under 35 U.S.C. §103(a) be withdrawn.

***Double Patenting***Claims 37-41\* and 43-48

Claims 37-41\* and 43-48 stand rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-36 of U.S. Patent 6,986,775. The Office Action states that the claims of the instant application are not patentably distinct from the claims of the '775 patent.

To obviate this rejection, Applicants have attached a Terminal Disclaimer (form PTO/SB/26), which disclaims (except as noted) the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of U.S. Pat. No. 6,986,775. Accordingly, Applicants request that the rejection of claims 37-41 and 43-48 on the ground of nonstatutory obviousness-type double patenting be withdrawn. Applicants submit that the pending claims are in immediate condition for allowance.

Claims 37-41\* and 43-48

Claims 37-41\* and 43-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-100 of co-pending Application Serial No. 11/237,461. Applicants will consider filing a terminal disclaimer after receiving an indication that each of the currently rejected claims is allowable. Until then, Applicants have no real way of assessing the merits of the double patenting rejection or determining whether the filing of a terminal disclaimer is appropriate.

Claims 37-41\* and 43-48

Claims 37-41\* and 43-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 37-46 of co-pending Application Serial No. 12/131,841. Applicants will consider filing a terminal disclaimer after receiving an indication that each of the currently rejected claims is allowable. Until then,

Applicants have no real way of assessing the merits of the double patenting rejection or determining whether the filing of a terminal disclaimer is appropriate.

Claims 37-41\* and 43-48

Claims 37-41\* and 43-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 58-94 of co-pending Application Serial No. 12/132,375. Applicants will consider filing a terminal disclaimer after receiving an indication that each of the currently rejected claims is allowable. Until then, Applicants have no real way of assessing the merits of the double patenting rejection or determining whether the filing of a terminal disclaimer is appropriate.

### **CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.



In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 578492000510. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 5, 2009

Respectfully submitted,

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